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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/186,775	11/06/1998	DIANE BURGESS	012176-00621	2248

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EXAMINER

HELMER, GEORGIA L

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 12/03/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/186,775

Applicant(s)

BURGESS ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,7,11,12,14-16,18,20,21,25,26 and 28-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1,2,4,6,7,11,12,14-16,18,20,21,25,26 and 28-37 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED OFFICE ACTION

Status of the Claims

1. The Office acknowledges receipt of Applicants Response, dated June 20, 2002, paper number 22.
2. Applicant has cancelled claims 3, 13, 17, and 27, and amended claims 1 and 14. Claims 1-2, 4, 6, 7, 11, 12, 14-16, 18, 20, 21, 25, 26, and 28-37 are pending, and are examined in the instant action.
3. This action is made FINAL necessitated by Applicant's amendment.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 first paragraph

6. Claims 1-2, 4, 6, 7, 11, 12, 14-16, 18, 20, 21, 25, 26, and 28-37 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record, as set forth in the Office Action mailed March 1, 2002. Applicant's arguments filed June 20, 2002 have been fully considered but are not deemed persuasive.

Applicant traverses asserting that methods of transforming plant cells are well known in the art and that the specification provides guidance for

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making expression vectors that express the nucleases of the invention, and selecting promoters for express of the nucleases in plants. Applicant has amended the claims to recite that the polynucleotides encoded complementary amino acid subsequences of a nuclease, which when expressed, produce a functional nuclease polypeptide. Applicant argues that the specification provides guidance for how to make and use two nonfunctional nuclease subsequences. The Gutterson Declaration filed May 18, 2000, provides experimental evidence that the claimed lethal effect is produced in transgenic plant cells expressing the nuclease subsequences (Response, p. 7-8, 11). Examiner responds the Gutterson Declaration does provide experimental evidence of the claimed lethal effect. However, the Gutterson Declaration does not address the real issue, which is the use of the claimed Recombinase systems.

Applicant has amended the claims to recite "impair" cell function, rather than "modify" cell function. Applicant asserts that the specification provides adequate guidance for methods of impairing cell function. Impaired cell function is defined at pages 4-5 of the specification, and the Gutterson Declaration filed May 18, 2000, provides evidence of impaired cell function in plant cells. Examiner responds the "impair" as defined at pages 4-5 includes the idea of cytotoxicity and lethality, and since Applicant has shown cell lethality as discussed above, is appropriate.

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Further, Applicant argues that the Kilby reference cited in the 103(a) rejection is evidence of the availability and workability of recombinase systems (Response, p 10). Examiner responds, with respect to the allegedly inconsistent rejections under 35 U.S.C. 112 and 35 U. S. C. 103, that the test for adequacy of a prior art disclosure to anticipate or render claims obvious is not the same test as that for adequacy of a patent application disclosure to support claims under 35 U. S. C. 112, as taught In re Hafner, 161 USPQ 783, (CCPA 1969). Examiner further responds that the major issues continue to be the unpredictability of recombinase systems, as stated in the previous office action. The issue is the unpredictability of using recombinase systems for generating particular phenotypes, and the production of chimeric phenotypes. Applicant has not provided sufficient guidance to practice the claimed methods utilizing recombinase systems, and in the absence of empirical evidence, it is not clear that the claimed methods can be used to make transgenic plants wherein the claimed phenotypic effects are produced.

Accordingly, the rejection is maintained.

7. Applicant is invited to submit evidence supporting the successful deployment of the claimed recombinase systems in a 1.132 Declaration.

Remarks

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

December 1, 2002
Georgia L. Helmer Ph.D.
Patent Examiner
AU 1638



AMY J. NELSON, PH.D.
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